NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CONSTANCE ROBINSON, AS SURVIVING SPOUSE AND ADMINISTRATRIX OF THE ESTATE OF LEONARD ROBINSON, DECEASED, Plaintiff, v. BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S. L.L.C., SANOFI-AVENTIS U.S., INC., SANOFI-SYNTHELABO, INC., Defendants.	Civil Action No. 3:07-cv-267 (FLW) **OPINION**

This matter comes before the Court on a motion to dismiss pursuant to Rules 12(b)(6) and 9(b) of the Federal Rules of Civil Procedure brought by defendants, Bristol Myers-Squibb Company, Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc., (collectively, "Defendants"). Plaintiff Constance Robinson ("Plaintiff"), as surviving spouse and administratrix of the Estate of Leonard Robinson ("Decedent"), brings the instant suit on behalf of Decedent against Defendants because she alleges that Decedent suffered injuries as a result of Defendants' unlawful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and sale of the prescription drug Plavix®. Plaintiff's First Amended Complaint asserts claims against Defendants for: (1) strict liability - defective design (Count I); (2) strict liability - manufacturing defect (Count II); (3) strict liability - failure to warn (Count III); (4) negligence (Count IV); (5) negligent misrepresentation (Count V); (6)

violations of Maryland's Consumer Protection Act (Count VI); (7) punitive damages (Count VII); (8) wrongful death (Count VIII); and (9) survival action (Count IX). Defendants' motion to dismiss is limited to Counts V and VI of Plaintiff's Complaint. For the reasons that follow, Counts V and VI are dismissed without prejudice.

I. Procedural History

On January 17, 2007, Plaintiff, a Maryland resident, filed a Complaint against Defendants asserting claims under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1, *et seq*., the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, *et seq*., the New Jersey Punitive Damages Act, N.J.S.A. 2A:15-5.9, *et seq*., New Jersey's Uniform Commercial Code, N.J.S.A. 12A:2-313, and the common law of the State of New Jersey, invoking this Court's diversity jurisdiction. (Jan. 17, 2007 Complaint ¶¶ 6-8.) Plaintiff is one of twenty-three individual claimants[1] that lodged separate complaints[2] against Defendants in this district between October 2006 and March 2007, invoking this Court's diversity jurisdiction and asserting similar claims under New Jersey law based upon injuries allegedly suffered as a result of Defendants' alleged negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and/or the sale of Plavix. Id. A brief recitation of the procedural history in the related matters is necessary to a full understanding of the prolonged procedural history in this matter.

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[1] Initially, claims were filed on behalf of twenty-four individual claimants, however, a Michigan plaintiff in the matter of Felmlee v. Bristol-Myers Squibb Co., No. 06-6240, voluntarily dismissed her claim in February, 2008.

[2] A number of the twenty-three claimants were joined in their actions by spouses, asserting claims for loss of consortium.

In January 2007, Defendants filed motions to dismiss pursuant to Fed.R.Civ.P. 12(b)(6) in the matters of Hall v. Bristol-Myers Squibb, No. 06-CV-5203 (hereinafter, "Hall"), and Skilstaff v. Bristol-Myers Squibb, No. 06-CV-4965 (hereinafter, "Skilstaff"),[3] and indicated their intention to file similar motions in the other Plavix cases pending before this Court. In March 2007, this Court, without objection from the parties, administratively terminated Defendants' motions in Hall and Skilstaff having determined that two cases then pending before the New Jersey Supreme Court addressed the central issues to be decided by this Court on Defendants' motions to dismiss. The parties further agreed that all Plavix cases filed in this district be held in abeyance. Following the issuance of the New Jersey Supreme Court's decisions in Rowe v. Hoffman-LaRoche, 189 N.J. 615 (2007), and International Union of Operating Engineers, Local #68 v. Merck, 192 N.J. 372 (2007), the plaintiff in Skilstaff voluntarily dismissed the action and this Court granted Defendants' request to file a single omnibus motion to dismiss applicable to all personal injury Plavix lawsuits then pending in this district.

One of the main issues to be determined by this Court in the omnibus motion was the federal preemption of the plaintiffs' individual state law claims. In February 2008, however, in light of the fact that the Third Circuit had pending two separate cases, Colacicco v. Apotex, Inc., and McNellis ex. rel. DeAngelis v. Pfizer, Inc., on its docket regarding substantially similar preemption issues, as did the United States Supreme Court, Levine v. Wyeth, this Court administratively terminated the personal injury Plavix

[3] The plaintiff in the matter of Skilstaff v. Bristol-Myers Squibb, is not among the twenty-three individual claimants seeking damages for personal injuries, rather Skilstaff was an Alabama third-party payor seeking certification of a class of third-party payors for violations of the New Jersey Consumer Fraud Act.

cases pending in this district and permitted plaintiffs to re-file amended complaints in the event there were viable claims after the decisions from the Higher Courts. Following the issuance of the Supreme Court's decision in Levine v. Wyeth, __ U.S. __, 129 S.Ct. 1187, 173 L.Ed. 2d 51 (2009), this Court reinstated the closed cases and, on May 1, 2009, each of the plaintiffs filed an amended complaint. In the amended complaints, each individual plaintiff brought claims under the laws of the states in which they reside, rather than New Jersey, as originally plead. Thereafter, Defendants moved to dismiss certain counts of the amended complaint filed by each individual plaintiff. It is the Defendants' motion to dismiss Counts V and VI with regard to this Plaintiff that this Court now considers.

II. Factual Background

The following version of events assumes Plaintiff's allegations in the First Amended Complaint ("FAC") to be true because Defendants move pursuant to Fed.Civ.R.P. 12(b)(6). The Court will recount only those facts relevant to this Motion.

Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc. (collectively, the "Sanofi Defendants") partnered with Bristol-Myers Squibb Company ("BMS") to manufacture and market Plavix in the United States. FAC ¶¶ 2-4. In April 1997, the Sanofi Defendants and BMS applied for a rare, priority regulatory review by the Food and Drug Administration ("FDA") clearing the way for Defendants to bring Plavix to market in November 1997. Id. at ¶ 11. According to Plaintiff, Defendants heavily marketed Plavix directly to consumers through television, magazine, and Internet advertising, falsely touting Plavix "as a 'super-aspirin' that would give a person even greater cardiovascular benefits than a much less expensive, daily aspirin, while being safer and easier on a person's stomach than aspirin." Id. at ¶ 13. Plaintiff alleges that

Defendants either knew or should have known, based upon their own studies, that not only was Plavix not more efficacious than aspirin in terms of preventing heart attacks and strokes, the risk of suffering a heart attack, stroke, internal bleeding, blood disorder or death far outweighed any benefit from the drug. Id. at ¶ 14.

As evidence that Defendants were indeed aware of their false and misleading promotion of Plavix, Plaintiff points to a November 1998 letter from the FDA wherein the FDA instructed Defendants to cease promoting Plavix for off-label use in patients undergoing coronary artery stent placement.[4] Id. at 18; Certification of Michele A. DiMartino, Esq. ("DiMartino Cert.") at ¶ 4, Ex. C. Plaintiff also points to the same FDA reprimand wherein Defendants were instructed to cease promoting Plavix at an off-label dose, which was nearly four (4) times that of the recommended dosage. FAC at ¶ 18; DiMartino Cert. ¶ 4, Ex. C. In addition to criticizing Defendants for promoting Plavix for unapproved use, the FDA also criticized Defendants for overstating the safety profile of Plavix with respect to its use with other drugs. Id. at ¶ 19. In particular, Plaintiff points to the fact that Defendants touted the safety of Plavix when combined with aspirin (known as "dual therapy") when, in fact, its safety had not been established. Id. According to Plaintiff, Defendants' claim regarding the safety of dual therapy has now been proven to be untrue in a recent study published in the New England Journal of Medicine in April 2006 entitled Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization,

[4] As discussed more fully infra, the Court will consider the extrinsic documents referenced in the FAC as they were explicitly relied upon by Plaintiff in the FAC.

Management, and Avoidance (the "CHARISMA Study"[5]). FAC at ¶ 19; DiMartino Cert. at ¶ 3, Ex. B.

As further evidence of Defendants' allegedly false and misleading promotional practices, Plaintiff points to a December 1998 letter from the FDA, wherein the FDA demanded that Defendants cease the distribution of advertising materials that claimed that Plavix has been proven more effective than aspirin. FAC at ¶ 20; DiMartino Cert. at ¶ 2, Ex. A. The FDA criticized Defendants' materials as an overstatement of efficacy, which was unsubstantiated and lacking in fair balance. Id. Again in 2001, the FDA ordered Defendants to immediately cease distribution of promotional material that made false or misleading claims about Plavix. FAC at ¶ 21; DiMartino Cert. at ¶ 5, Ex. D. Specifically, the FDA noted that the clinical evidence of the efficacy of Plavix is derived from Defendants' study entitled Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events Trial (the "CAPRIE Study"). Id. Defendants' promotional material depicted a 19.2% relative risk reduction for Plavix versus aspirin, yet the actual findings of the CAPRIE Study were that Plavix was not proven significantly more effective than aspirin. Id. Additionally, the FDA again instructed Defendants to cease claiming that the use of Plavix combined with aspirin was safe and effective. Id.

According to Plaintiff, in addition to misinforming physicians and consumers through false and misleading promotional materials and advertising, Defendants' drug representatives also misinformed physicians regarding the proper types of patients who should be prescribed Plavix, the duration of its proper usage and the applications for which

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[5] The CHARISMA Study derives its name from the Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance trial, which was the subject of the article.

Plavix is safe and FDA approved. FAC at ¶ 22. Specifically, Plaintiff points to the fact that the drug representatives have encouraged physicians to prescribe Plavix to a broad population who would receive the same therapeutic benefit from aspirin alone, without the purported risk of death, and to use Plavix for unapproved applications. Id. at ¶ 23.

Plaintiff alleges that after a nearly eight-year run of misleading physicians and the public regarding the safety and efficacy of Plavix, scientific studies now reveal that Plavix is in fact dangerous. Id. at ¶ 25. Citing a study published in The New England Journal of Medicine in January 2005 entitled Clopidogrel versus Aspirin and Esomeprazole to Prevent Recurrent Ulcer Bleeding (the "Chan Study"), Plaintiff notes the dangers of Plavix. Specifically, Plaintiff contends that the Chan Study demonstrates the fallacy of Defendants' assertions that Plavix is safer and more effective for patients suffering from gastrointestinal intolerance to aspirin. Id. at ¶ 26. Plaintiff points out that the Chan Study recommended that prescribing guidelines for Plavix be changed so that patients would not erroneously believe that Plavix is safer on the stomach than aspirin, in light of the Study's findings that recurring stomach bleeding was 8.6% in the Plavix group versus only .7% in the aspirin group. Id. Plaintiff additionally points to the Chan Study's finding that an aspirin a day plus esomeprazole (the generic name for an inexpensive over-the-counter proton pump inhibitor such as Prilosec) is far more cost effective than paying for the four-dollar per day Plavix pill, which greatly increases the risk of stomach bleeding. Id. at ¶ 27. Finally, citing the CHARISMA Study, Plaintiff contends that Plavix plus aspirin ("dual therapy") is only minimally more effective than aspirin plus placebo at preventing atherothrombotic events, and more significantly, does more harm than good in those patients without peripheral arterial disease or acute coronary syndrome in that it poses a

20% increased risk to the patient of suffering bleeding injuries, heart attacks, stroke and death. Id. at ¶ 28.

Plaintiff alleges that Decedent "was taking Plavix in combination with aspirin – 'dual therapy' – which caused him to suffer a brain hemorrhage and die on January 19, 2004." ¶ 30.

III. Standard of Review

When reviewing a motion to dismiss on the pleadings, courts "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." Phillips v. County of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008) (citation and quotations omitted). In Bell Atlantic Corporation v. Twombly, 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007), the Supreme Court clarified the 12(b)(6) standard. Specifically, the Court "retired" the language contained in Conley v. Gibson, 355 U.S. 41, 45-46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957), that "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Id. at 561 (quoting Conley, 355 U.S. at 45-46). Instead, the factual allegations set forth in a complaint "must be enough to raise a right to relief above the speculative level." Id. at 555. As the Third Circuit has stated, "[t]he Supreme Court's Twombly formulation of the pleading standard can be summed up thus: 'stating … a claim requires a complaint with enough factual matter (taken as true) to suggest' the required element. This 'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of 'the necessary element'."

Phillips, 515 F.3d at 234 (quoting Twombly, 550 U.S. at 556).

In affirming that Twombly standards apply to all motions to dismiss, the Supreme Court recently explained the principles. "First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949, 173 L.Ed. 2d 868 (2009); Fowler v. UPMC Shadyside, 578 F.3d 203, 210-11 (3d Cir. 2009).[6] "Second, only a complaint that states a plausible claim for relief survives a motion to dismiss." Id. at 1950. Therefore, "a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." Id. Ultimately, "a complaint must do more than allege the plaintiff's entitlement to relief. A complaint has to 'show' such an entitlement with its facts." Fowler, 578 F.3d at 211.

Before reaching the merits of Plaintiff's claims, there is a threshold procedural question as to the documents and exhibits this Court may consider on this motion to dismiss pursuant to Fed.R.Civ.P. 12(b)(6). As previously referenced in this Court's discussion of the Factual Background, Plaintiff supplies this Court with several exhibits, including: (1) a December 1998 FDA letter addressed to Sanofi Pharmaceuticals, Inc.; (2) a copy of the CHARISMA Study; (3) a November 1998 FDA letter addressed to Sanofi Pharmaceuticals, Inc.; (4) a May 2001 FDA letter addressed to Sanofi-Synthelabo Inc.; and (5) the Chan Study. Additionally, the Defendants provide the Court with the November 17, 1997 approval letter for Plavix. Certification of Michael A. Tanenbaum, Esq., Ex. A. While

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[6] The Court notes that because the briefing in this matter was filed only shortly after the United States Supreme Court's decision in Ashcroft v. Iqbal, 129 S. Ct. 1937 (2009), counsel for Defendants moved for leave to file supplemental briefing addressing the standard of review applicable to the instant motion. This Court found additional briefing unnecessary and, accordingly, denied Defendants' request.

generally a court may not consider matters outside the pleadings when ruling on a motion to dismiss, documents that are "integral to or explicitly relied upon in the complaint" may indeed be considered without converting a motion to dismiss into a motion for summary judgment. In re Rockefeller Ctr. Props., Inc. Sec. Litig., 184 F.3d 280, 287 (3d Cir.1999) (emphasis and citations omitted). Accordingly, the referenced exhibits are properly before the Court on the instant motion to dismiss.

IV. Plaintiff's Claim Under Maryland's Consumer Protection Act

In Count VI of Plaintiffs' FAC, Plaintiff asserts violations of Maryland's Consumer Protection Act, Md. Code Ann. Com. Law, § 13-101, *et seq*. ("MCPA"). The MCPA prohibits a person from engaging in an unfair or deceptive trade practice including any "false, falsely disparaging, or misleading oral or written statement, visual description, or other representation of any kind which has the capacity, tendency, or effect of deceiving or misleading consumers." Md. Code Ann. Com. Law, § 13-301(1). A private right of action to recover for injury and loss from a forbidden practice is available under § 13-408 of the MCPA only when a party can show actual injury or loss sustained as a result of the unfair or deceptive practice. Citaramanis v. Hallowell, 328 Md. 142, 152, 613 A.2d 964, 969 (Md. 1992).

Citing to Morris v. Osmose Wood Preserving, 340 Md. 519, 529-30, 667 A.2d 624, 630 (Md. 1995), Defendants argue that reliance is a necessary element to a claim when the unfair and deceptive trade practice is a representation or omission of fact. Def. Br. at 3. Plaintiff disputes Defendants' assertion that reliance is a necessary component to an MCPA claim. According to Plaintiff, Morris simply does not stand for that proposition as the court's reference to reliance was only an "allusion to an implication of the trial court's

ruling." Pl. Br. at 6. The Court need not resolve that issue on the instant motion, however, because as discussed infra the FAC fails to satisfy the particularity requirements with regard to other elements of the MCPA claim.

Plaintiff asserts that Rule 9(b) is inapplicable to the MCPA claim because a Plaintiff need not establish fraud under § 13-301(1). Pl. Br. at 8. However, courts within the District of Maryland have indeed applied Rule 9(b) to claims brought under the MCPA where, as here, fraud is at the heart of the alleged violations of the MCPA. See Johnson v. Wheeler, 492 F.Supp.2d 492, 509 (D.Md. 2007) (finding that heightened pleading standards of 9(b) apply where "fraud is at the heart of Defendant's alleged violations of the [MCPA]"); Haley v. Corcoran, __ F.Supp.2d __, No. WDQ-09-1338, 2009 WL 3163528, * 6 (D.Md. Oct. 2, 2009). See also In re Suprema Specialities, Inc. Securities Litig., 438 F.3d 256, 270 (3d Cir. 2006) (noting that where "plaintiff grounds [his claims] in allegations of fraud - and the claims thus 'sound in fraud' - the heightened pleading requirements of Rule 9(b) apply").

In Frederico v. Home Depot, 507 F.3d 188 (3d Cir. 2007), the Third Circuit elucidated what must be alleged to satisfy the heightened pleading standard of Rule 9(b):

> Pursuant to Rule 9(b), a plaintiff alleging fraud must state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the "precise misconduct with which [it is] charged." To satisfy this standard, the plaintiff must plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation.

Id. at 200 (*internal citations omitted*). The Court finds the FAC woefully deficient. As Defendants indicate, Paragraph 30 of the FAC is the only paragraph in the entire FAC that provides specific details regarding Decedent and the allegations therein are limited to a description of Decedent's injuries. The remaining factual allegations in the FAC are

boilerplate allegations that appear in all twenty-three of the amended complaints filed by the personal injury Plavix plaintiffs in this district. The allegations within Count VI of the FAC do not remedy the deficiency. The allegations amount to nothing more than conclusory allegations purporting to set forth the elements of the MCPA claim. There is absolutely no plaintiff-specific information identified in Count VI. As to causation, Plaintiff simply states:

> 105. As a direct and proximate cause of the Defendants' acts of consumer fraud, the Plaintiff has suffered ascertainable loss - economic loss that includes the purchases of Plavix and additional out-of-pocket healthcare related costs, for which the Defendants are liable to Plaintiff for treble [sic] Plaintiff's actual damages.
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> 106. As a direct and proximate cause of the Defendants' acts of consumer fraud, the Plaintiff further suffered severe and permanent physical injuries.

Citing U.S. ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co., 147 F.Supp. 2d 39, 49 (D.Mass.2001), Plaintiff urges this Court to find that the circumstances present in this case warrant the relaxation of the particularity requirements of Rule 9(b). Pl. Br. at 12. To the extent that Rule 9(b)'s requirements may be relaxed, the Court finds relaxation inappropriate here. The facts necessary to satisfy Rule 9(b) are not facts which are in Defendants' control. Rather, what Plaintiff has failed to allege are those facts that demonstrate that the purported deceptive practices were the proximate cause of Decedent's and Plaintiff's injuries.[7] While it is true that when reviewing a motion to dismiss, the

[7] Indeed, in that connection, Plaintiff is uniquely equipped to determine from Decedent's prescribing physician, whether the physician received such promotional literature or information from Defendants' sales representatives. Even where factual information may be within the domain or control of Defendants, Plaintiff must still "accompany [his] legal theory with factual allegations that make [his] theoretically viable

Court must construe the complaint in the light most favorable to the plaintiff, Phillips, 515 F.3d at 233, in the absence of specific facts in the FAC that Decedent or his prescribing physician had any exposure to the promotional materials that the FDA demanded Defendants discontinue disseminating some three to six years prior to Decedent's prescription, the Court simply cannot find the particularity requirements have been met. Accordingly, Plaintiff's MCPA claim cannot withstand the instant motion to dismiss.[8]

V. Plaintiff's Negligent Misrepresentation Claim

To maintain a claim of negligent misrepresentation under Maryland law, "a plaintiff must show:

> (1) the defendant, owing a duty of care to the plaintiff, negligently asserts a false statement;
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> (2) the defendant intends that his statement will be acted upon by the plaintiff;
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> (3) the defendant has knowledge that the plaintiff will probably rely on the statement, which, if erroneous, will cause loss or injury;
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> (4) the plaintiff, justifiably, takes action in reliance on the statement; and
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> (5) the plaintiff suffers damage proximately caused by the defendant's

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claim plausible." In re Burlington Coat Factory, 114 F.3d 1410, 1418 (3d Cir. 1997). Moreover, to "avoid dismissal," a complaint must also delineate at least the nature and the scope of a plaintiff's efforts to obtain, before filing the complaint, the information needed to plead with particularity. Shapiro v. UJB Financial Corp., 964 F.2d 272, 285 (3d Cir. 1992). Plaintiff has failed to comply with these requirements. Plaintiff's FAC makes no allegations that the information required for Plaintiff to meet her Rule 9(b) obligation is solely within Defendants' control.

[8] Defendants also sought dismissal of Plaintiff's punitive damages claim to the extent it sought punitive damages under the MCPA. In light of this Court's dismissal of Plaintiff's MCPA claim, this Court need not address the issue, however, the Court notes that Plaintiff has asserted in response that she seeks only those damages to which she is entitled.

negligence."

Baltimore County v. Cigna Healthcare, 238 FedAppx. 914, 921 (4th Cir. 2007) (*citing* Griesi v. Atl. Gen. Hosp. Corp., 360 Md. 1, 756 A.2d 548, 553 (Md. 2000)). The parties do not dispute that to sustain a claim for negligent misrepresentation, Plaintiff must establish that Defendants owed a duty of care to Plaintiff's Decedent. Defendants argue that Plaintiff is unable to establish the existence of such a duty given that Maryland courts have adopted the learned intermediary doctrine. Def. Br. at 8. Citing Weinberger v. Bristol-Myers Company, 652 F.Supp. 187, 189-90 (D.Md. 1986), wherein the court noted "[i]n the area of prescription drugs . . . it is well established that the manufacturer's duty to warn is limited to advising the prescribing or treating physician of the drug's potential dangers", Defendants argue that their duty runs to the prescribing physician and not to Plaintiff, Decedent or to the general public. Id.

The Court rejects Defendants' suggestion that the learned intermediary doctrine operates here to bar Plaintiff's negligent misrepresentation claim. When determining whether the doctrine applies, there are two relevant inquiries: "were the label warnings themselves adequate? If not, was the prescribing physician adequately warned from another source?" Ames v. Apothecon, Inc., 431 F.Supp. 2d 566, 572 (D.Md. 2006). "The doctrine countenances the learned intermediary's entire field of knowledge, however gained. Even if a label's warnings are inadequate, the doctrine protects a manufacturer from liability provided the doctor has been sufficiently warned from other sources." Id. In light of the factual inquiry in which the Court must engage to ascertain the doctrine's applicability, the Court fails to see how the doctrine could be applied to bar Plaintiff's claim at this stage in the proceedings.

Next, the Court turns to Defendants' contention that dismissal is warranted because Plaintiff has failed to plead with the specificity required by Rule 9(b). In support of its application, Defendants cite Orteck International Inc. v. Transpacific Tire & Wheel, Inc., DKC-2005-2882, 2006 WL 2572474, *20 (D.Md. Sep. 5, 2006) wherein a district court noted that the Fourth Circuit has yet to definitively rule on the applicability of the heightened pleading standard of Rule 9(b) to negligent misrepresentation claims. While Orteck International Inc., 2006 WL 2572474, *20 is indeed among a number of courts within the District of Maryland that have applied Rule 9(b) to negligent misrepresentation claims, the Fourth Circuit has since addressed the issue and determined that the heightened pleading requirements of Rule 9(b) do not apply to claims of negligent misrepresentation under Maryland law. Indeed, in Baltimore County v. Cigna Healthcare, 238 FedAppx. at 921, the Fourth Circuit held that because a negligent misrepresentation claim under Maryland law "does not contain an essential showing of fraud," the heightened pleading standard does not apply.[9]

Even under the more lenient standards of Rule 8(a), however, Plaintiff's negligent misrepresentation claim cannot withstand the instant motion to dismiss. Last year, addressing the clarifications as to a litigant's pleading requirement stated by the United States Supreme Court in Twombly, 550 U.S. 544, the Court of Appeals for the Third Circuit provided the district courts with guidance as to what pleadings are sufficient to pass muster under Rule 8. See Phillips v. County of Allegheny, 515 F.3d at 230-34. Specifically,

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[9] The Court cautions that to the extent Plaintiff intends to seek this Court's leave to file a second amended complaint, it must be clearly averred that the negligent misrepresentation claim is premised upon a theory of negligence, and does not sound in fraud, to avoid application of Rule 9(b).

the Third Circuit, quoting Twombly, observed as follows:

> "[W]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's [Rule 8] obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." . . . "[T]he threshold requirement of Rule 8(a)(2) [is] that the 'plain statement' possess enough heft to 'sho[w] that the pleader is entitled to relief.'" . . . "Factual allegations must be enough to raise a right to relief above the speculative level."

Phillips 515 F.3d at 231-32 (quoting Twombly 550 U.S. at 555). As previously noted, this pleading standard was further refined by the United States Supreme Court in Ashcroft v. Iqbal, 129 S. Ct. 1949 wherein the Supreme Court held that in all civil actions:

> [T]he pleading standard Rule 8 announces . . . demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation. . . . The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are "merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility of 'entitlement to relief.'"
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> . . . .
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> Two working principles underlie [the] decision in Twombly. First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice. . . . Rule 8 . . . does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions. Second, only a complaint that states a plausible claim for relief survives a motion to dismiss. Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged - but it has not "show[n]" - "that the pleader is entitled to relief." Fed. Rule Civ. Proc. 8(a)(2).
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> . . . .

> Rule 8 does not empower [a claimant] to plead the bare elements of his cause of action, affix the label "general allegation," and expect his complaint to survive a motion to dismiss.

Iqbal, 129 S.Ct. at 1949-54 (quoting Twombly 550 U.S. at 555-57). Since Iqbal, the Third Circuit has required the district courts to conduct, with regard to Rule 8 allegations, a two-part analysis when presented with a motion to dismiss:

> First, the factual and legal elements of a claim should be separated. The District Court must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions. [See Iqbal, 129 S.Ct. at 1949-50]. Second, a District Court must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a "plausible claim for relief" [in light of the definition of "plausibility" provided in Iqbal.] In other words, a complaint must do *more than allege the plaintiff's entitlement to relief*. A complaint has to "show" such an entitlement with its facts. See Phillips, 515 F.3d at 234-35. As the Supreme Court instructed in Iqbal, "[w]here the well-pleaded facts do not permit the court to infer more than the *mere possibility of misconduct, the complaint has alleged-but it has not 'show [n]'-'that the pleader is entitled to relief.'"* Iqbal, 129 S.Ct. at 1949-50. This "plausibility" determination will be "a context-specific task that *requires the reviewing court to draw on its judicial experience and common sense."* Id.

Fowler, 578 F.3d at 210-11 (emphasis supplied).

This Court finds that Plaintiff has failed to plead anything other than bald conclusory allegations in support of the negligent misrepresentation claim. As previously noted, the only factual allegations in the FAC which are not boilerplate and which provide details with regard to Decedent are those in Paragraph 31, wherein Plaintiff describes the fact that Decedent was prescribed Plavix to be taken in combination with aspirin. FAC at ¶ 30. With regard to Decedent's own experiences, or those of his prescribing physician, in connection with Defendants' purported false and misleading promotional materials and

practices, Plaintiff is silent. Even if this Court were to find that Plaintiff has plead facts sufficient to support the first three elements of the claim, it is clear that the FAC does not set forth sufficient facts to support the remaining elements – justifiable reliance and causation. The FAC sets forth the following allegations with regard to those elements:

> 81. Defendants' misrepresentations were made to Plaintiff's decedent, as well as the general public. Plaintiff's decedent and his healthcare provider justifiably relied on Defendants' misrepresentations and consequently, Leonard Robinson's ingestion of Plavix was to his ultimate detriment.
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> 82. Defendants' misrepresentations proximately caused Plaintiff's decedent's injuries and death and as a result, Plaintiff has also suffered damages and monetary loss.

The conclusory nature of Plaintiff's allegations mandates dismissal of the claim. While Plaintiff made exhaustive allegations regarding Defendants' alleged illegal practices by relying on FDA correspondence and scientific studies, the FAC fails to allege any facts linking Defendants' conduct with Decedent's and Plaintiff's resultant injuries, or setting forth the alleged misrepresentations of fact received and relied upon by Decedent and his prescribing physician. Plaintiff fails to even identify Decedent's prescribing physician. The necessary factual allegations to support Plaintiff's claim are not the sort that are within the control of, and therefore subject to concealment by Defendants. Accordingly, Plaintiff has failed to state a claim upon which relief can be granted.

VI. Conclusion

For the foregoing reasons, Counts V and VI of Plaintiff's FAC are dismissed without prejudice. Plaintiff shall have leave to file a motion to amend the complaint if she seeks to assert the claims, but she must cure the deficiencies as outlined by the Court herein.

Dated: December 30, 2009

/s/ Freda L. Wolfson
United States District Judge